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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,829	08/05/2005	Shai Amisar	4110-34	4361
23117	7590	05/04/2007		
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER BRITTINGHAM, JOHN M	
			ART UNIT 3709	PAPER NUMBER
			MAIL DATE 05/04/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/509,829

Applicant(s)

AMISAR ET AL.

Examiner

John M. Brittingham

Art Unit

3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/30/2004; 5/12/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: IDS 3/1/2007.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4-8, 12-15, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bodicky (USPN 4,333,455). The patent to Bodicky discloses a catheter introducer system for introducing a catheter into a body passageway and delivering intravenous medicament to the patient.

3. In regards to claims 1 and 2, Bodicky ('455) discloses a multi-use port element (52) having a bore (58) and a hub (55) configured for transcutaneous positioning and liquid flow communication with a vein (figures 2 and 3), removable needle (60) from entry port element, needle hub (63). A flexible catheter tube (22) with a hub (26), an aperture (39) and a slide adaptor-connector (24) designed to allow catheter (22) slidable insertion through the port element into a vein of a patient (Figure 7 and Col. 4, lines 26-55).

4. In regards to claim 4, Bodicky ('455) discloses a second end of the cannula (52) formed with a taper (54) providing a compression lip seal for the catheter (22).

5. In regards to claims 5 and 7, Bodicky ('455) discloses a slide adaptor-connector and connector element (24) have a Leur Lock ( Col. 3, lines 67-68 and Col. 4, lines 1-2).

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6. In regards to claim 6, Bodicky ('455) discloses a catheter (22) with a connector element (26), removable cap (28 and 30), configured to connect to an intravenous therapeutic device (68, 168, 268, and 468), a slidable connector element (24) configured to connect with the entry port element ( Col. 4, lines 26-55).
7. In regards to claim 8, Bodicky ('455) discloses an integral sterile environment containment element (20) enclosing the catheter ( Col. 3, lines 48-58).
8. In regards to claim 12, Bodicky ('455) discloses a selectably operable locking device ( Col. 4, lines 55-61).
9. In regards to claim 13, Bodicky ('455) discloses an entry-port element with a valve for regulating a flow of liquid through the catheter tube ( figure 7 and No. 32).
10. In regards to claims 14 and 15, Bodicky ('455) discloses an intravenous cannula element, first and second ends and a bore formed therebetween configured for transcutaneous positioning. a self-contained sterile catheter apparatus, a first and second ends and a flexible catheter tube with a predetermined length therebetween, a connector element, removable cap, slidable-connector element, a diameter adapted for slidable insertion through said bore of said intravenous cannula element into the body organ of the subject, and an integral sterile environment containment element (Col. 3, lines 44-68 and Col. 4, 26-55).
11. In regards to claim 18, Bodicky ('455) discloses a method for introducing an improved intravenous catheter system into a subcutaneous vein of a subject to include the steps of introducing entry port, withdrawing needle, advancing entry port into vein, connecting a catheter device and slidably inserting flexible catheter-tube through the entry-port into the Subcutaneous vein of the subject (Col. 4, lines 2-55).

*Claim Rejections - 35 USC § 103*

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 3, 19, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodicky ('455) in view of Feller et al. (USPN 4,362,156).

15. Bodicky ('455) teaches the limitations of claims 1, 2 and 18. However, concerning claims 3 and 19, Bodicky lacks mounting lugs to secure the catheter to the subject. Feller ('156) discloses entry-port element (10) with mounting lugs (60) to secure the entry-port element to the subject (66 and Col. 6, lines 20-24). Mounting lugs are well known in the art and thus it would have been obvious for one of ordinary skill in the art to modify Bodicky's catheter system with mounting lugs to secure catheters to a subject to prevent unintended displacement and ensure continued access to the patient for reliable delivery of medicaments.

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16. Concerning claims 20 and 21, Bodicky lacks a method to partially withdraw the piercing needle and removing the stiffener element. Feller ('156) discloses a method to partially withdraw the removable piercing-needle from the entry-port (Col. 4, lines 56-58 and Col. 5, lines 1-29) and slidably removing the stiffener element from the catheter (Col. 5, lines 1-29). It would have been obvious to one of ordinary skill in the art to practice the partial withdrawal of the piercing needle and slidably remove a stiffener element as it has been well known in the art that the standard practice of partially removing the removable piercing needle from the entry port is to check on proper access and positioning within a subject's vessel and that a stiffener element or guidewire are slidably removed from a catheter after positioning and prior to using the catheter for delivering medicaments.

17. Claims 9-11 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodicky ('455) in view of Gray et al. (USPN 6,086,008).

18. Bodicky ('455) teaches the limitations of claims 1, 8, and 14. However, concerning claims 9, 10, and 16, Bodicky lacks a cylindrical housing and an apparatus for introduction and withdrawal of a catheter from a coiled configuration. Gray ('008) discloses a cylindrical housing (18) with a withdrawable coiled catheter (2) and a clutch device to control forceful insertion of the catheter tube through the entry port into a vein (Col. 5, lines 24-31). It is well known in the art for the need to control the forceful insertion of a catheter into a subject and would have been obvious to one of ordinary skill in the art to combine Bodicky's coiled catheter with Gray's cylindrical housing to enable controlled forceful insertion of a sterile catheter into a patient..

19. Concerning claims 11 and 17, Bodicky lacks a removable stiffener element. Gray ('008) discloses a removable stiffener element (7). It would have been obvious to one of ordinary skill

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in the art to modify Bodicky's catheter system with Gray's stiffener element because stiffener elements or guidewires are well known in the art to aid in the placement of catheters within a vessel.

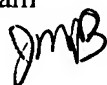
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John M. Brittingham whose telephone number is 571-270-1891. The examiner can normally be reached on M-TH 0730-1700, 1st FRI off, 2nd FRI 0830-1700 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

John Brittingham  
JMB  
3/28/2007



GARY JACKSON  
SUPERVISORY PATENT EXAMINER



4/27/2007